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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,301	04/20/2004	Michael B. Zemel	31894-202099	2573

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	
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09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,301	ZEMEL ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/08 has been entered.

Claims 1-18 are under examination.

Comment: The Examiner notes that a terminal disclaimer has been filed over this application in co-pending application 10/827353 and approved on 4/22/08.

Withdrawn rejections:

Applicant's amendments and arguments filed 6/18/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10-13 and 15-17 recite “at least about”. "At least" provides a static point (for example, at least 2.4% calcium) whereas "about" provides a dynamic point (for example, about 2.4% calcium which could mean 2.5%

calcium). The combination is then indefinite because one cannot have a static dynamic point. The claims will be examined as they read on "about".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metz et al. (AJH 1988, 1, 58-60) in view of Heinemann et al. US 5,538,743 and Science Daily 4/212/1999 (ref C13 supplied by Applicant on IDS filed on 2/13/08).

Applicant claims a method of regulating weight in an overweight non-human animal.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Metz et al. teach methods of modifying total body fat in rats by dietary calcium (up to 2% Ca++) and sodium (title and Abstract and Materials and Methods). Calcium is a diary product. Metz et al. teach that it is known that calcium has an effect on lipid metabolism (Abstract). Metz et al. clearly teach that dietary calcium produced consistent reductions in body weight in SHR and WKY rats (page 59, discussion). Thus, Metz et al. were aware of the link between dietary calcium and weight loss. Metz et al. teach that body fat and weight can be favorably modified by increasing the dietary content of both calcium and sodium (page 60, left column). Metz et al. teach that calcium's effects on blood pressure were sodium dependent which was the reason for utilize both Ca++ and Na+ in the study (page 60, left column). A rat can be a pet. A rat renders obvious other mammals. Rats live on farms and can be considered a farm animal. Ingestion of the calcium intrinsically reduces the risk of calcium related disorders. The method of Metz. et al. intrinsically treats or reduces obesity.

Science Daily teaches that ***calcium not only helps keep weight in check, but can be associated specifically with decreases in body fat*** (page 1).

Heinemann et al. teach a complete animal feed for cats and dogs in a package comprising about 75% by weight of a dairy component (Abstract and claims 1-10).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Metz et al. is that Metz et al. do not expressly teach maintaining the animal on a restricted diet below ad lib.

2. The difference between the instant application and Metz et al. is that Metz et al. do not expressly teach an animal food package comprising a container and a dietary plan.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to cut calories below ad lib and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because fewer ingested calories results in weight loss. The average person understands this concept. The more one restricts calories (70%) for longer periods of time, including about 6 weeks, it is expected that one will lose weight.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to package the composition of Metz et al. as suggested by Heinemann et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is obvious to package the composition for ease of use. With regards to the dietary plan limitation, the Examiner notes that the weight loss benefits of calcium were known in the art and do not present a new functional relationship. As such, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See ** Lowry, 32 F.3d **>at<

1583-84, 32 USPQ2d **>at< 1035 **; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant's arguments are moot with respect to the new rejection of record above. However, the Examiner will address the primary assertion of Applicant. Applicant asserts that any suggestion that Metz demonstrates a weight related benefit attributable to calcium is unfounded. The Examiner cannot agree. Clearly Metz et al. was aware of the teachings in the art, as discussed above and further evidenced by the art, such as the Science Daily article cited above, which teach that ***calcium not only helps keep weight in check, but can be associated specifically with decreases in body fat.***

The Examiner cannot be any more clear on the subject. The correlation between calcium and weight loss was known and established in the art before the filing of the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/918277. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches a method of regulating body weight by administering an effective amount of calcium thereby inducing weight loss. The copending application does not expressly teach maintaining the overweight animal on a restricted caloric diet. However, restricted caloric diets are obvious when weight loss is a goal. Therefore, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/091924. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches a method of regulating body weight by administering an effective amount of calcium containing whey product to induce weight or fat loss. The copending application does not expressly teach maintaining the overweight animal on a restricted caloric diet. However, restricted caloric diets are obvious when weight loss is a goal. Therefore, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-8, 22 and 24 of copending Application No. 10/827309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches a method of weight loss by consuming dietary calcium and maintaining a restricted caloric diet below ad lib which is cloaked behind a method of inducing consumption of calcium containing products for weight loss. The methods also teach preventing or reducing obesity and prevent or reduce weight gain. The copending

application does not expressly teach at least about 0.4% calcium in the method. However, the amount of calcium would be a result effective variable which one would optimize. The copending application does not expressly teach a packaged product in the method. However, the packaging the composition for ease of use would be obvious to one ordinary skill in the art. Therefore, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-17 and 19-22 of copending Application No. 10/827307. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches a method of inducing weight loss in an individual suffering from obesity by administering calcium containing products and restricting the caloric intake below ad lib. The methods also teach preventing or reducing obesity and prevent or reduce weight gain. The copending application does not expressly teach a packaged product in the method. However, the packaging the composition for ease of use would be obvious to one ordinary skill in the art. Therefore, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616